

## REMARKS

### Introduction

In view of at least the present remarks, applicant respectfully requests reconsideration and withdrawal of the rejections set forth in the Office Action and allowance of the pending claims.

### Claim Amendments

Independent Claims 1, 7, 37, 55, 68 and 81 have been amended to incorporate features of a "quick disconnect" therein. Support for these amendments may be found throughout the specification and drawings of the application as originally filed. No new matter has been added.

### Claim Rejections under 35 U.S.C. § 103(a)

The Patent and Trademark Office updated the MPEP in view of the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), to include guidelines for determining obviousness under 35 U.S.C. § 103(a) ("Guidelines"). The Guidelines provide that the steps set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), should be followed when determining obviousness. See MPEP § 2141(II). The four factual inquiries used in *Graham* as a background for determining obviousness include:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

Objective evidence and secondary considerations, such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts, are relevant to the issue of obviousness and must be considered in every case in which they are present. When evidence of any of these secondary considerations is submitted, the examiner must evaluate the evidence. See MPEP § 2141.

As noted in MPEP § 706.02(j), entitled "Contents of a 35 U.S.C. 103 Rejection":

To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. (quoting *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)).

Also, as stated in MPEP § 2142, entitled "Legal Concept of Prima Facie Obviousness":

The legal concept of prima facie obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. . . The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.

....

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person.

Furthermore, as noted in MPEP § 2143.01, entitled "Suggestion or Motivation To Modify the References":

IV. MERE STATEMENT THAT THE CLAIMED INVENTION IS WITHIN THE CAPABILITIES OF ONE OF ORDINARY SKILL IN THE ART IS NOT SUFFICIENT BY ITSELF TO ESTABLISH PRIMA FACIE OBVIOUSNESS - A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

The Office bears the initial burden of factually supporting any rejection based on obviousness. If the Office does not establish a *prima facie* case, however, then the applicant is under no obligation to submit evidence of nonobviousness. MPEP § 2142.

For at least the following reasons, applicant submits that the Office has not established a *prima facie* case of obviousness against the pending claims, as amended, because the cited references, either individually or collectively, fail to teach or suggest each and every element of the pending claims.

The pending claims in the application have been rejected under this section based on various proposed combinations of Knobloch (U.S. Pat. No. 3,043,499), Robert (U.S. Pat. No. 5,566,781), Gargas (U.S. Pat. No. 4,684,334), and/or Raines (U.S. Pat. No. 4,246,932).

The Office Action states the following: “The patent to Knobloch et al., as modified by Robert et al., discloses all the claimed features with the exception of having a ‘quick disconnect operatively associated with at least one of said inlet/outlet ports.’ The patent to Raines discloses that it is known in the art to employ a ‘quick disconnect’ at the friction fit of the syringe and its inlet/outlet port at the end of the syringe with the ‘common refill/evacuation location’ chamber 100 for the purpose of permitting simple, easy, and repeatable connection of the inlet/outlet port to the refill/evacuation location. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Knobloch et al., as modified by Robert et al., a ‘quick disconnect’ connecting the end of conduit 4, 4a with the valve chest 5, 5a, respectively, for the purpose of permitting simple, easy, and repeatable connection of the inlet/outlet port 4, 4a to the refill/evacuation location 5, 5a, respectively, as recognized by Raines.” (see Office Action, pp. 14-15).

Applicant respectfully submits that the claim elements as recited in operative association with a “quick disconnect” feature are not taught, disclosed, or suggested by the cited references, whether taken alone or in combination. In one particular instance, applicant disagrees with the Office Action’s assertion that, “The patent to Raines discloses that it is known in the art to employ a ‘quick disconnect’ at the friction fit of the syringe and its inlet/outlet port at the end of the syringe with the ‘common refill/evacuation location’ chamber 100 for the purpose of permitting simple, easy, and repeatable connection of the inlet/outlet port to the refill/evacuation location.” Among other features, Raines does not possess an “inlet/outlet port” structured for performing fluid refill and evacuation processes.

Applicant submits that “at least one quick disconnect connection operatively associated with said inlet/outlet port” as recited in Claim 1, for example, is not taught, disclosed, or suggested by Raines. Also, the “inlet/outlet port” recited in Claim 1 is “in direct fluid communication with said inlet of said first check valve and in direct fluid communication with said outlet of said second check valve at the common refill/evacuation location.” The syringe described in Raines does not structurally or functionally correspond to a “quick disconnect connection” at a “common refill/evacuation location” and in operative association with an “inlet/outlet port” consistent with the recitation of Claim 1.

It seems to applicant that the syringe of Raines is only used as a mechanism to facilitate transfer of liquid from a source through a first valve disc in an aspiration procedure, to the interior of the valve assembly, and then onward through a second valve disc in an injection procedure. (See Raines - col. 1, lines 48-63). Raines does not function to refill or evacuate fluids through an “inlet/outlet port” at a “common refill/evacuation location” much less in operative association with a “quick disconnect connection” at the “common refill/evacuation location”. In contrast, Claim 1 recites “at least one quick disconnect connection operatively associated with said inlet/outlet port” and “the inlet/outlet port in direct fluid communication . . . at the common refill/evacuation location.” In summary, the cited references do not teach, suggest, or disclose the combination of an “inlet/outlet port” at a “common refill/evacuation location” and in operative association with a “quick disconnect connection”.

As noted above, independent Claims 1, 7, 37, 55, 68 and 81 have been amended to incorporate features of a “quick disconnect” therein. Claims 7, 37, 55, 68 and 81 are

allowable for reasons analogous to those stated above with respect to Claim 1. Applicant submits that the claims depending from the independent claims (where applicable) are allowable for at least the same reasons as the independent claims. Reconsideration and withdrawal of the rejections set forth in the Office Action are respectfully requested based on at least the present remarks.

#### Reservation of Arguments

These amendments have been made without prejudice or disclaimer to the subject matter of the claims as originally filed. Furthermore, applicant does not acquiesce or otherwise concede the correctness of the rejections to the previously presented claims. Accordingly, applicant reserves the right to pursue the subject matter of the claims as previously presented or as originally filed in the application in related applications that may be currently on file or filed at a later date. Moreover, applicant reserves the right to submit in such related applications arguments made in connection with the present application. These amendments have been made primarily for the purpose of expediting prosecution of the present application.

Applicant does not concede the correctness of the Office Action rejections with respect to any of the independent or dependent claims. Applicant reserves the right to make additional or supplemental arguments as may be necessary because the independent and dependent claims include additional features that further distinguish the claims from the cited references. A detailed discussion of these differences is unnecessary at this stage in view of the fundamental distinctions pointed out above. Applicant does not acquiesce to any of the specific

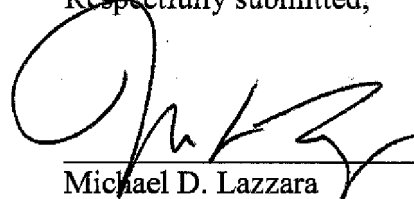
rejections, assertions, and statements presented in the Office Action that have not been explicitly addressed herein. Applicant reserves the right to specifically address all such rejections, assertions, and statements in continuing applications, subsequent responses, and in appeal or pre-appeal proceedings.

CONCLUSION

Applicant requests reconsideration of the Office Action rejections and allowance of the pending claims of the present application. To expedite prosecution of the application, applicant requests a supplemental interview if in the Examiner's view any issues with the application remain outstanding.

Any questions regarding the present response are invited to the attention of the undersigned representative by telephone.

Respectfully submitted,



Michael D. Lazzara  
Reg. No. 41,142

K&L GATES LLP  
K&L Gates Center  
210 Sixth Avenue  
Pittsburgh, Pennsylvania 15222-2613

Telephone: (412) 355-8994  
Fax: (412) 355-6501  
E-mail: [michael.lazzara@klgates.com](mailto:michael.lazzara@klgates.com)

Customer No. 26285